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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,376	09/29/2000	Anand R. Baichwal	540.1040	1823

7590

06/18/2003

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Appli cation No.

09/676,376

Applicant(s)

BAICHWAL ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-69 and 71-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-69 and 71-119 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of request for extensions of time (granted) filed with notice of appeal on 3-4-03 and with amendment filed 3-17-03 is acknowledged. Claims 1-13 and 15-64 have been canceled and new claims 73-119 have been added as requested.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11-6-02 was entered as indicated by the Advisory Action of 12-17-02.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 65-69, 71-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (WO 97/26865; hereafter '865) in view of Baichwal et al (5,399,359; hereafter '359).**

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4. '865 teaches methods for making sustained release xanthan gum/locust bean gum compositions comprising mixtures of gel strength enhancing agents that are also pH modifying agents such as organic acids (see page 6, line 21 through page 7, line 15). The compositions are produced by mixing an excipient of homopolysaccharide and heteropolysaccharide gums and gel strength enhancing agents along with other excipients such as inert diluents, surfactants, hydrophobic material, mixing the excipient with therapeutically active agents and then compressing the mixture into tablets. '865 does not specifically teach the solubility limitations or the actives of the instant claims. Therefore, '359 is relied upon for teaching the benefits of homopolysaccharide and heteropolysaccharide gum sustained release formulations for the instant active agents with the motivation of providing sustained release formulations for these compounds. '865 also does not teach that the organic acid is specifically mixed with active agent in a step separate from mixing of homopolysaccharide and heteropolysaccharide gums. However, the procedure of '865 ultimately provides a combined mixture of all the components together, as do the instant claims. In other words, the final product is the same regardless of the sequence of addition of the components (i.e. the sequence is not critical). Accordingly, such a change in sequence does not impart patentability upon the claims as in *Ex parte Rubin*, 128 USPQ 440 (Bd. Appeals 1959) and *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Requirement that the organic acid facilitates release of medicament does not impart patentability over the cited references since it is the position of the examiner that the organic acid of the prior art facilitates the controlled

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release (therefore the release) of the active agent and no definition for facilitation of medicament release is provided in the instant specification or claims.

***Response to Arguments***

5. It is first noted that the manner of combination of the references has been changed along with some reasons for finding non-obvious. As applied to this new rejection, Applicant's arguments filed 3-17-03 have been fully considered but they are not persuasive. Applicant argues that '865 is directed to sustained release formulations that prevent an initial burst of active medicament and that this is different from the instant claims that require facilitated release of active agent from the dosage form. However, the phrase "facilitates the release of said medicament" does not impart patentability over '865. No definition for the manner in which release of the medicament is facilitated is provided and this phrase alone does not distinguish that facilitation does not occur through aiding in release of active in a controlled manner.

**6. Claims 108-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (WO 97/26865; hereafter '865) in combination with Baichwal et al (5,399,359; hereafter '359) and further in combination with Baichwal et al (5,478,574; hereafter '574).**

7. '865 and '359 are relied upon for all that they teach as previously stated.

8. '574 teaches inclusion of a surfactant in xanthan gum/locust bean gum compositions provides a bimodal or multi-phase controlled release of a therapeutically

active ingredient. '574 also teaches that such xanthan gum/locust bean gum compositions are effective for delivering active agents such as diltiazem.

9. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '359 and '574 to achieve a bimodal or multi-phase controlled release of a therapeutically active ingredient in a strong formulation.

### ***Response to Arguments***

10. It is first noted that the manner of combination of the references has been changed along with some reasons for finding non-obvious. As applied to this new rejection, Applicant's arguments filed 3-17-03 have been fully considered but they are not persuasive. It appears Applicant relies upon the response to arguments for those claims rejected over '865 in view of '359, stating that '574 does not overcome the deficiencies of this rejection. As stated *supra* in paragraph 9, such argument is not found persuasive. Those reasons for finding such argument not persuasive are again relied upon here. It is the position of the Examiner that the organic acid facilitates the release of medicament by aiding in the medicament's controlled release.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

tw

June 15, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600